



Docket No. 26648

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

|  |                        |                  |
|--|------------------------|------------------|
|  | Application Number     | 10/696,044       |
|  | Filing Date            | October 29, 2003 |
|  | First Named Inventor   | Robert M. Noack  |
|  | Art Unit               |                  |
|  | Examiner Name          |                  |
| Total Number of Pages in This Submission | Attorney Docket Number | 00903            |

### ENCLOSURES (Check all that apply)

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|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form                                | <input type="checkbox"/> Drawing(s)                                       | <input type="checkbox"/> After Allowance Communication to a Technology Center (TC)      |
| <input type="checkbox"/> Fee Attached  | <input type="checkbox"/> Licensing-related Papers                         | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
| <input type="checkbox"/> Amendment/Reply                                     | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final   | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information  |
| <input type="checkbox"/> Affidavits/declaration(s)                           | <input type="checkbox"/> Power of Attorney, Revocation                    | <input type="checkbox"/> Status Letter  |
| <input type="checkbox"/> Extension of Time Request                           | <input type="checkbox"/> Change of Correspondence Address                 | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):         |
| <input type="checkbox"/> Express Abandonment Request                         | <input type="checkbox"/> Terminal Disclaimer                              | <input checked="" type="checkbox"/> Return Postcard                                     |
| <input checked="" type="checkbox"/> Information Disclosure Statement         | <input type="checkbox"/> Request for Refund                               |   |
| <input type="checkbox"/> Certified Copy of Priority Document(s)              | <input type="checkbox"/> CD, Number of CD(s) _____                        |   |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application    |   |   |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 |   |   |
| Remarks  |   |   |

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|                    |                                  |  |
|--------------------|----------------------------------|--|
| Firm or Individual | Karen B. King<br>Reg. No. 41,898 |  |
| Signature          |                                  |  |
| Date               | March 9, 2004                    |  |

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450 on this date March 9, 2004

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| Typed or printed | Connie L. Park     |
| Signature        |                    |
|                  | Date March 9, 2004 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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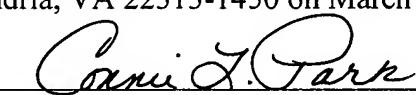
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robert M. Noack et al ) DOCKET NO.: 00903  
                                       ) )  
SERIAL NO.: 10/696,044           ) GROUP ART UNIT:  
                                       ) )  
FILED: October 29, 2003          ) EXAMINER:  
                                       )  
TITLE: ORAL EXTENDED RELEASE TABLETS AND METHODS OF  
                                       MAKING AND USING THE SAME  
DATE: March 9, 2004

CERTIFICATE OF MAILING

I hereby certify that this document and accompanying documents referred to herein are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 9, 2004.

  
Connie L. Park

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97(b)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit copies of patents, publications or other information of which they are aware that they believe may be material to the examination of this application, and in respect of which there may be a duty to disclose under 37 CFR § 1.56. A list of all enclosed documents is provided in a PTO Form 1441, transmitted herewith.

This information disclosure statement is being filed within three months of the filing date of the above-cited patent application or prior to the mailing of a first Office action on the merits, in accordance with 37 CFR § 1.97(b). Accordingly, Applicants

respectfully request that the statement be considered by the Office, in the course of prosecution of the application.

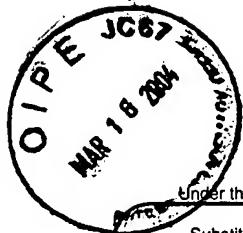
The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR §1.97(g)), an admission that the information cited is or is considered to be, material to patentability, or that no other material information exists.

Dated: 3/9/04



Karen B. King  
Reg. No.: 41,898

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Sheet

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| Art Unit               | Not Yet Known          |
| Examiner Name          | Not Yet Known          |
| Attorney Docket Number | 00903/1/US             |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Document Number                                       | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|--------------------|-----------------------|---|--------------------------------|--|---|
|                    |                       | Number-Kind Code <sup>2</sup> ( <sup>if known</sup> ) |                                |  |   |
|                    |                       | US- 3,885,026   | 05/20/75                       | H. Heinemann et al.                                |   |
|                    |                       | US- 4,096,238   | 06/20/78                       | A. Zaffaroni et al.                                |   |
|                    |                       | US- 4,134,943   | 01/16/79                       | K. Knitsch et al.                                  |   |
|                    |                       | US- 4,244,941   | 01/13/81                       | C. Lerk  |   |
|                    |                       | US- 4,687,660   | 08/18/87                       | R. Baker et al.                                    |   |
|                    |                       | US- 4,837,030   | 06/06/89                       | J. Valorose et al.                                 |   |
|                    |                       | US- 4,871,549   | 10/03/89                       | Y. Ueda et al.                                     |   |
|                    |                       | US- 4,880,631   | 11/14/89                       | J. Haslam et al.                                   |   |
|                    |                       | US- 4,892,742   | 01/09/90                       | N. Shah  |   |
|                    |                       | US- 4,919,938   | 04/24/90                       | C. Lovegrove et al.                                |   |
|                    |                       | US- 4,946,686   | 08/07/90                       | G. McClelland et al.                               |   |
|                    |                       | US- 4,994,273   | 02/19/91                       | G. Zentner et al.                                  |   |
|                    |                       | US- 5,055,306   | 10/08/91                       | B. Barry et al.                                    |   |
|                    |                       | US- 5,102,665   | 04/07/92                       | A. Schaeffer                                       |   |
|                    |                       | US- 5,175,003   | 12/29/92                       | R. Goldman   |   |
|                    |                       | US- 5,260,069   | 11/09/93                       | C. Chen  |   |
|                    |                       | US- 5,356,467   | 10/18/94                       | B. Oshlack   |   |
|                    |                       | US- 5,458,887   | 10/17/95                       | C. Chen et al.                                     |   |
|                    |                       | US- 5,505,966   | 04/09/96                       | P. Edman et al.                                    |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document  | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>Or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|--|--------------------------------|--|---|----------------|
|                    |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <sup>if known</sup> ) |                                |  |   |                |
|                    |                       | WO 90/01926  | 03/08/90                       | Himedics, Inc.                                     |   |                |
|                    |                       | WO 93/00889  | 01/21/93                       | L.C. Phar-Chem LTD.                                |   |                |
|                    |                       | WO 94/22431  | 10/13/94                       | Kabi Pharmacia AB                                  |   |                |
|                    |                       | WO 97/25979  | 07/24/97                       | Perio Products LTD                                 |   |                |
|                    |                       | WO 98/03161  | 01/29/98                       | Dexcel LTD   |   |                |
|                    |                       | WO 98/15265  | 04/16/98                       | Danbiosyst UK Limited                              |   |                |

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Sheet

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| First Named Inventor   | Robert M. Noack et al. |
| Art Unit               | Not Yet Known          |
| Examiner Name          | Not Yet Known          |
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|---|-----------------------|-----------------|--------------------------------|--|---|
| <i>Number-Kind Code<sup>2</sup> (# known)</i> |                       |                 |                                |  |   |
|   |                       | US- 5,520,931   | 05/28/96                       | C. Persson et al.                                  |   |
|   |                       | US- 5,607,685   | 03/04/97                       | M. Cimbollek et al.                                |   |
|   |                       | US- 5,609,884   | 03/11/97                       | S. Desai   |   |
|   |                       | US- 5,656,294   | 08/12/97                       | D. Friend et al                                    |   |
|   |                       | US- 5,656,296   | 08/12/97                       | S. Khan et al.                                     |   |
|   |                       | US- 5,670,170   | 09/23/97                       | F. Grimmett et al.                                 |   |
|   |                       | US- 5,711,967   | 01/27/98                       | R. Juch  |   |
|   |                       | US- 5,840,332   | 11/24/98                       | E. Lerner et al.                                   |   |
|   |                       | US- 5,881,388   | 03/16/99                       | K. Pratt et al                                     |   |
|   |                       | US- 5,900,252   | 05/04/99                       | M. Calanchi et al.                                 |   |
|   |                       | US- 6,004,581   | 12/21/99                       | S. Jepsen et al.                                   |   |
|   |                       | US- 6,068,856   | 05/30/00                       | G. Sachs et al.                                    |   |
|   |                       | US- 6,068,859   | 05/30/00                       | W. Curatolo et al.                                 |   |
|   |                       | US- 6,074,669   | 06/13/00                       | V. Nagaprasad et al.                               |   |
|   |                       | US- 6,150,410   | 11/21/00                       | K. Engh et al.                                     |   |
|   |                       | US- 6,228,398   | 05/08/01                       | J. Devane et al.                                   |   |
|   |                       | US- 6,231,888   | 05/15/01                       | E. Lerner et al.                                   |   |
|   |                       | US- 6,287,599   | 08/11/01                       | B. Burnside et al.                                 |   |
|   |                       | US- 6,312,728   | 11/06/01                       | E. Beiman et al.                                   |   |

**FOREIGN PATENT DOCUMENTS**

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| <i>Country Code<sup>3</sup>-Number<sup>4</sup>-Kind Code<sup>5</sup> (if known)</i> |                       |                         |                                |  |   |                |
|   |                       | WO 98/22095             | 05/28/98                       | Procter & Gamble Co.                               |   |                |
|   |                       | WO 98/26767             | 06/25/98                       | Poli Industria Chimica S.P.A.                      |   |                |
|   |                       | WO 99/00136             | 01/07/99                       | J. Rowe  |   |                |
|   |                       | WO 99/66904             | 12/29/99                       | Theratech Inc.                                     |   |                |
|   |                       | WO 00/25757             | 05/11/00                       | Merck & Co., Inc.                                  |   |                |
|   |                       | WO 00/69420             | 11/23/00                       | Coraltis Ltd.                                      |   |                |

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|--------------------|-----------------------|---|--------------------------------|--|---|----------------|
|                    |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                    |                       | WO 01/05430 A1  | 01/25/01                       | Merck & Co., Inc.                                  |   |                |
|                    |                       | WO 01/45706   | 06/28/01                       | Pharmacia Corporation                              |   |                |
|                    |                       | EP 0 310 814  | 10/06/87                       | American Cyanamid Co.                              |   |                |
|                    |                       | EP 0 365 947 B1   | 05/02/90                       | DIB Limited  |   |                |
|                    |                       | EP 0 572 942  | 12/08/93                       | Monsanto Italiana S.p.A.                           |   |                |

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| Examiner<br>Signature |  | Date<br>Considered |  |
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| <b>Attorney Docket Number</b> | 00903/1/US             |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  | T <sup>2</sup> |
|--------------------|-----------------------|--|----------------|
|                    |                       | LEE F. SIEW, ABDUL W. BASIT, AND J. MICHAEL NEWTON, "The Potential of Organic-Based Amylose-Ethylcellulose Film Coatings as Oral Colon-Specific Drug Delivery Systems", AAAPS PharmSciTech, 2000, 9 pages, 1 (3), article 22, The School of Pharmacy, London, UK |                |
|                    |                       | SURELEASE, Product Information, Product Specification, Formula No. E-7-19010, (2001), Colorcon, 2 pages  |                |
|                    |                       | SURELEASE, Technical Data; Coating Application, (2001), Colorcon, 2 pages  |                |
|                    |                       | SURETERIC, Product information; Product Data Sheet; Formula: YAE-6-18107, (2000), Colorcon, 2 pages  |                |
|                    |                       | BILL ST. JOHN, "Controlled Delivery Oral Dosage Forms in the New Millennium", Pharmaceutical Manufacturing and Packing Sourcer, © 2000, 4 pages, Ballantyne Ross Ltd International Media, London, UK   |                |
|                    |                       | ZEIN, 3 pages, downloaded from internet at www.freeman@lanline.com on 9/6/2002, Freeman Industries LLC, (last modified 6/13/2002)  |                |
|                    |                       | ACRYL-EZE, Technical Data Sheet; Enteric Coating Stability, (2001), Colorcon, 2 pages  |                |
|                    |                       | SURETERIC, Information sheet, Preparation & Use Guidelines; © 2001 Colorcon, 2 pages   |                |
|                    |                       | FUKUI ET AL., "Preparation of enteric coated timed-release press-coated tablets and evaluation of their function by in vitro and in vivo test for colon targeting", Int. J. of Pharm., 19 May 2000, pages 7-15, vol. 204   |                |
|                    |                       |  |                |

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